K112319

JAN 27 2012

510K summary

Company Name:	Electro-Cap International, Inc. 1011 West Lexington Road P.O. Box 87 Eaton, OH 45320
Contact:	Amy B. Swallows
Phone:	937-456-6099
Fax:	937-456-7323

Summary Date:	January 19, 2012
Trade Name:	Electro-Cap System
Common Name:	EEG Electrode Positioning System
Classification Name:	Electrode, Cutaneous
Regulation Number:	21 CFR 882.1320
Product Code:	GXY

Predicate Device(s):

510(k) Number:	K780045
Manufacture:	Electro-Cap International, Inc.
Trade Name:	Electro-Cap System

510(k) Number:	K071446
Manufacture:	Electrode Arrays
Trade Name:	Electrode Array Cap

510(k) Number:	K000865
Manufacture:	Neuroscan (Neurosoft, Inc.)
Trade Name:	Quik-Cap EEG Electrode Positioning System Cap

510(k) Number:	K110223
Manufacture:	Eemagine Medical Imaging Solutions GmbH
Trade Name:	WaveGuard EEG Cap

1.0 Description of Device

The Electro-Cap System is an EEG electrode positioning system used to quickly place the standard 20 EEG electrodes and also a large number of electrodes in a uniform and consistent manner on the head and body in order to transmit electrophysiological signals from an individual to data collection devices. The Electro-Cap is made from a spandex type material with recessed electrodes in plastic mounts attached to the cap. The standard cap covers the entire scalp and is held in place with chin straps, or with cap straps attached to a body harness. The Surgical Cap material is cut slightly different to allow the cap to fit securely over the ears to hold

it in place. The spandex type material holds the electrodes securely in position during an EEG recording. Wires are attached to each electrode and exit the cap to form a cable, which is used to connect the cap to the EEG equipment, either through an adapter cable, or in some instances, directly to the equipment with the connector on the cap. The electrical activity of the brain is transferred through the Electro-Gel to the recessed electrode and then to the EEG or computer equipment for evaluation.

The electrodes on the standard caps are positioned to the International Ten-Twenty System (10-20) of Electrode Placement. In addition, Electro-Caps with as few as 2 or as many as 256 electrodes, have been built with the placement of the electrodes conforming to the 10-10 American Electrocencephalographic Society positioning system. Electro-Caps are also produced based on customer specified electrode placements, with electrodes made of either tin or silver/silver chloride, gold plated or silver. Dropped wires, small mounts, thin mounts and customized wiring and connectors offer additional options

2.0 Intended Use of Device

The Electro-Cap is intended for use in routine clinical settings where rapid placement of a number of EEG electrodes is desired.

3.0 Predicate Comparison

The Electro-Cap has the same technological characteristics as the predicate devices. It serves as a matrix electrode pathway between the scalp/conductive gel and the EEG recorders. The design of the Electro-Cap System is in conformance with AAMI Standards Specifications for ECG Cables and Lead-Wires and Other Devices that use Patient Cables, EC53-1995, and the IEC Standard 60601-1 Subclause 56.3, (c). Like the predicates the Electro-Cap consists of a stretch fabric cap, metal disk electrodes, electrode holders and electrode lead wires.

Technologically, the Electro-Cap functions in exactly in the same manner as the predicate devices. The electrode holder is a two part component made of Polyethylene which allows the 2 parts to snap together with the fabric between. The electrode lead wires are on the inside of the standard caps giving the technician easy access to the electrodes without interference of the lead wires.

Available Electro-Cap Options:

A list of the various options which the company offers is shown below. It is important to recognize that all variants carry the same intended use, fundamental scientific technology and clinical considerations:

Size of caps, babies to extra large (26 to 66cm).
Regular or surgical style caps. Special cut (low front or back).
Number of electrodes: Density and placement to conform to International 10/20 electrode placement system and /or the 10-10 American Electrocencephalographic Society positioning system.
Ear Slits.
Electrode mounts: Standard, Small and thin.

Types of electrode drops, detachable/non-detachable.
Size of electrode drops or separate lead wires: 9mm, 6mm, Bio-Potential, Ear clip.
Electrode metals: Tin, Silver/Silver Chloride, Gold Plated or Silver.
Caps with electrode placement holes only.
Caps with electrode mounts only.
Caps with electrodes and electrode mounts only, no lead wires.
Caps with outside wiring on the cap.
Caps complete except for connectors.

All Electro-Caps use the same ribbon cable but may have fewer or more wires in the cable to match the number of electrodes on the cap, individual lead wires or shielded lead wires.

All Electro-Caps use the same type of D-Sub connectors except the connectors may have 10 to 80 pin or sockets, or other commercially available connectors as required by the customer that will allow the caps to be plugged directly into their EEG equipment.

Accessories:

As stated on the Company's Certificate to Foreign Government as well as listed with the FDA, the Electro-Cap System uses the following accessories:

E1 Electro-Caps
E2 Electro Board Adapter
E3 Body Harness
E4 Quick Insert Electrodes
E5 Ear Electrodes
E6 Disposable Sponge Disk
E7 Needle/Syringe Kit
E8 Special Blunted Needle
E12 Head Measuring Tape
E13 Cap Straps
E16 Ivory Detergent
E17 Bio-Potential Electrode
E19 Spare Electrode Disk
E20 Spare Electrode Mounts
E21 Disk Electrode
E22 Extra Placement on Cap
E23 Chin Straps
E24 Chin Straps Pads
E25 Adhesive Electrode Pads
E26 Orange Sticks
E27 Disposable ECG Electrode
E28 Alligator Clip Adapter
E40 Converter Pin/Socket
I 1 Infa Caps
I 2 Infa Body harness
I 3 Infa Head Measuring Tape

(Please refer to the comparison table on the following three pages.)

4.0 SPECIFICATIONS/COMPARISONS TO PREDICATE DEVICES

Table 4.0 compares features and specifications of the proposed Electro-Cap System, including additional research features to the previously approved Electro-Cap System and the the Electrode Array Cap manufactured by Electrode Arrays and WaveGuard EEG Cap by Eemagine Medical Imaging Solutions GmbH and the Quik Cap by Neuroscan, Inc.

Table 4.0: Comparison to Predicate Devices

Feature	ELECTRO-CAP SYSTEM 510(k) # K112319	Electro-Cap System (Predicate) 510(k) # K780045	Electrode-Array Cap (Predicate) 510(k) # K071446	Eemagine Medical Imaging Solutions GmbH (Predicate) 510(k) # K110223	Quik-Cap Neuroscan, Inc. (Predicate) 510(k) # K000865	Substantial Equivalence Comments
Indication for Use	The Electro-Cap is intended for use in routine clinical settings where rapid placement of a number of EEG electrodes is desired.	The Electro-Cap is intended for use in routine clinical settings where rapid placement of a number of EEG electrodes is desired.	The Electrode Array Cap is intended for routine clinical settings where rapid placement of large numbers of EEG electrodes is desired.	This is an EEG electrode set intended for intended for routine clinical settings where rapid placement of large numbers of EEG electrodes is desired.	The Quik-Cap is intended for the same use as the predicate Electro-Cap and is intended for routine clinical settings where rapid placement of large numbers of EEG electrodes is desired.	Electro-Cap has the same/equivalent Indication for Use as predicates
Environment of Use	Electrophysiological	Electrophysiological	Electrophysiological	Electrophysiological	Electrophysiological	Same as predicates
Intended user	Neurologists	Neurologists	Neurologists	Neurologists	Neurologists	Same as predicates
Target Patient	Adults and Children	Adults and Children	Adults and Children	Adults and Children	Adults and Children	Same as predicates
Where Used	On the head	On the head	On the head	On the head	On the Head	Same as predicates
Number of Contacts	2 - 256	20	1 to 256	1 to 256	12 to 256	Same as/equivalent the predicates
Size of Caps	Various- babies to Large 26 cm to 66 cm	Various- Extra Small to Large 46cm to 62 cm	Various- children to Large 44 cm to 62 cm	Various- babies to Large 25cm to 61 cm	Various- babies to Large 34cm to 65 cm	Same as/equivalent the predicates
Style of Caps	Full Head Cap	Full Head Cap	Full Head Cap	Full Head Cap	Full Head Cap	Same as predicates
Ear Slits	Yes	No	Yes	Yes	Yes	Same as/equivalent the predicates

4.0 SPECIFICATIONS/COMPARISONS TO PREDICATE DEVICES

Cap Material	Spandex	Spandex	Light Duty Lycra	Elastic Coolmax	Heavy Duty Lycra	Same as/equivalent the predicates
Electrode Mounts	Polyethylene	Polyethylene	PVC	Silicone	Rubber Material	Same as/equivalent the predicates
Location of Wiring	Inside Cap	Inside Cap	Inside Cap	Inside Cap	Outside Cap	Same as predicates
Cable Length	Various – 3 to 5 feet	3 feet	1 Foot	Not Available	5 Feet	Same as/equivalent the predicates
Type of Cables	Standard Ribbon Cable and Lead Wires	Standard Ribbon Cable and Lead Wires	Shielded Lead Wires	Shielded Lead Wires	Standard Ribbon Cable and Lead Wires	Same as/equivalent the predicates
Type of Electrode Drop	Detachable and Non Detachable	Detachable and Non Detachable	Non Detachable	Non Detachable	Non Detachable	Same as predicates
Electrode Metal	Pure Tin, Silver, Silver/Silver Chloride, Gold Plated	Pure Tin	Silver/Silver/Chloride	Silver/Silver/Chloride	Tin, Silver, Silver/Silver Chloride, Gold and AgCL	Same as/equivalent the predicates
Type of Connectors	D-Sub Connectors, Touch Proof Din Sockets and Special Connectors to Match EEG Equipment and Computers	D-Sub Connectors , Touch Proof Din Sockets and Special Connectors to Match EEG Equipment and Computers	Alden Pulse Lok Connectors, Touch proof Din Sockets and D-Sub Connectors and Track-it connectors.	D-Sub Connectors 25 and 35 pins.	D-Sub Connectors , Touch Proof Din Sockets and Special Connectors to Match EEG Equipment and Computers	Same as/equivalent the predicates
Biocompatibility Testing	None was conducted	None was conducted	None was conducted	Nonclinical test	None was conducted	Same as most Predicates

4.0 SPECIFICATIONS/COMPARISONS TO PREDICATE DEVICES

Performance Requirements	Needs to transmit electrophysiological signals from an individual to data collection devices with a maximum impedance of 5K/Ohms. Does not transmit electrical current, nor are they intended to be used for stimulation.	Needs to transmit electrophysiological signals from an individual to data collection devices with a maximum impedance of 5K/Ohms. Does not transmit electrical current, nor are they intended to be used for stimulation.	Needs to transmit electrophysiological signals from an individual to data collection devices with a maximum impedance of 5K/Ohms. Does not transmit electrical current, nor are they intended to be used for stimulation.	Needs to transmit electrophysiological signals from an individual to data collection devices with a maximum impedance of 5K/Ohms. Does not transmit electrical current, nor are they intended to be used for stimulation.	Needs to transmit electrophysiological signals from an individual to data collection devices with a maximum impedance of 5K/Ohms. Does not transmit electrical current, nor are they intended to be used for stimulation.	Same as predicates
Manufacturing Methods	Caps sewn and assembled internally. Lead wires purchased from FDA approved manufacturer.	Caps sewn and assembled internally. Lead wires purchased from FDA approved manufacturer.	Caps sewn by third party vendor. Lead wires purchased from FDA approved manufacturer.	Not Available	Not Available	Same as/equivalent the predicates
Type of Additional Electrodes	Various metal Disk Electrodes for Reference. Electrodes made from Tin, Gold Plated, Silver and Silver/Silver Chloride.	Disk Electrodes (Pure Tin Cups) for Reference. May be attached with ear clips or Adhesive Electrode Pads.	Not available	Not Available	Various metal Disk Electrodes for Reference. Electrodes made from Tin, Gold Plated, Silver and Silver/Silver Chloride.	Same as/equivalent the predicates

4.0 Comparison Summary

As shown above in Table 4.0, the proposed device is identical/equivalent in all aspects to the predicates. The inclusion of the variant parameters demonstrates that the device itself is manufactured for the same intended use, on the same patient population with equivalent manufacturing methods and technologies.

4.0 Conclusions

A comparison of the technological characteristics demonstrates that the device is substantially equivalent to the legally marketed predicated devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Electro-Cap International, Inc.
c/o Ms. Amy Swallows
Director of Marketing
1011 West Lexington Road
PO Box 87
Eaton, OH 45320

SEP 14 2012

Re: K112319
Trade/Device Name: Electro-Cap System
Regulation Number: 21 CFR 882.1320
Regulation Name: Cutaneous Electrode
Regulatory Class: Class II
Product Code: GXY
Dated: December 20, 2011
Received: December 21, 201

Dear Ms. Swallows:

This letter corrects our substantially equivalent letter of January 27, 2012.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Kesia Alexander

Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic, Neurological,
and Ear, Nose and Throat Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K112319

Device Name: Electro-Cap System

Indications for Use:

The Electro-Cap System is intended for use in routine clinical and research settings where rapid placement of a number of EEG electrodes is desired.

Prescription Use __X__ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Duynh Hoang

(Division Sign-Off)
Division of Ophthalmic, Neurological and Ear, Nose and Throat Devices

510(k) Number K112319